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09/583,336	05/31/2000	William F. Reeves		2397

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EXAMINER

KALINOWSKI, ALEXANDER G

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 06/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/583,336

Applicant(s)

Reeves

Examiner
Alexander Kalinowski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 31, 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. Claims 1-28 are presented for examination. Applicant filed a petition to make special which was granted on 5/20/2002.

Specification

2. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Objections

3. Claim 12 is objected to because of the following informalities: typographical error.

In claim 12, line 1, after "to" delete --2--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, it is unclear to the Examiner what the limitation of "software for

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controlling the internal logic of the portable field unit and the patient monitoring module and the base unit" refers to. Is the claim directed to control software that is located in each of the claimed portable field unit and patient monitoring module and base unit devices where each of the software modules controls the operation of each of the respective devices ? Or is the claim directed to the software of the system used to control the flow and processing of information to and from each of the claimed portable field unit and patient monitoring module and base unit devices when using the devices to carry out the claimed invention? For purposes of applying prior art, the limitation as best understood by the Examiner will be interpreted to mean being directed to the flow and processing of information when using the claimed devices (i.e. bodily worn device 21, Interface wand 20, portable field unit 19, base unit 18) to carry out Applicant's claimed invention (see specification on page 6, line 28 - page 7, line 10 and Fig. 3).

a. Claims 2-15 are rejected on a similar basis to claim 1 based on their dependency to claim 1.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeager et al., WO 97/22297 (hereinafter Yeager) and Sellers, Pat. No. 5,678,562.

As to claim 1, Yeager discloses an apparatus for storing and/or retrieving and/or organizing medical records and other vital personal information from bodily worn storage devices (i.e. medical information storage system including a portable data storage device worn by a person)(see abstract, Fig. 1), comprising:

a bodily worn storage device capable of storing digitized (digital) personal medical records and other vital personal emergency information (i.e. portable data storage device unit 22 includes datacell which contains medical information specific to person wearing device)(page 5, lines 5-15, line 28 - page 6, line 2 and Table 1)

a portable field unit with a unique interface wand capable of retrieving digital patient records and information from the bodily worn device and transmitting said digital information by wireless means (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion)(page 5, lines 18-23)

a base unit capable of receiving said digital medical records and information and organizing them into readable and medically significant information for emergency medical treatment options (i.e. handheld reader displays the medical data on the display screen including conditions, medications, allergies ... communication interface 156 can optionally communicate with a remote data terminal to provide access to database system 76 or to a local hospital or

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emergency medical center for data transmission for emergency room notification)(page 13, lines 5-14 and 17-30).

software for digitizing, organizing and displaying said critical patient information in page formats for emergency medical treatment and other applications and usage (i.e. medical records database system for generating, maintaining and updating personal medical information records)(see Fig. 7A and 7B and page 7, line 20 - page 8, line 10) and

software for controlling the internal logic of the portable field unit and the patient monitoring module and the base unit (see Fig. 1 and page 5)

Yeager does not explicitly disclose

a patient monitor module for interfacing the wireless critical patient information and data with an existing emergency room patient monitoring device

However, Sellers discloses a patient monitor module for interfacing the wireless critical patient information and data with an existing emergency room patient monitoring device (i.e. electronics module unit 20)(see Fig. 4, contacts in patient connector 18 are connected to analog circuit 50 and the analog circuit amplifies and processes ECG signals from the patient electrodes)(col. 5, lines 19-42). It would have been obvious to one of ordinary skill in the art at the time of the invention to include a patient monitor module for interfacing the wireless critical patient information and data with an existing emergency room patient monitoring device as disclosed by Sellers within the Yeager system for the motivation of providing a cheap and

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inexpensive system for transmitting medical information and personal information for emergency treatment (col. 2, lines 16-19 and lines 45-48).

As to claim 2, Yeager discloses the apparatus of claim 1 wherein the interface wand is capable of capturing said digital medical records by non-contact optical or wireless means (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion)(see Fig. 1 and page 5, lines 18-23)

As to claim 3, Yeager discloses the apparatus of claim 1 wherein the bodily worn device is capable of transmitting or receiving said digital medical records from the interface wand by non-contact optical or wireless means (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion)(page 5, lines 18-23).

As to claim 4, Yeager discloses the apparatus of claim 1 wherein the portable field unit is capable of receiving, storing and displaying said medical records on a lighted display screen via the interface wand (see Fig. 1 and Fig. 9).

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As to claim 5, Yeager discloses the apparatus of claim 1 wherein the portable field unit is capable of wireless transmission of the said digital medical records to said base unit (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion ... communication interface 156 can optionally communicate with a remote data terminal to provide access to database system 76 or to a local hospital or emergency medical center for data transmission for emergency room notification)(page 5, lines 18-23 and page 13, lines 5-14).

As to claim 6, Yeager discloses the apparatus of claim 1 wherein the portable field unit is programmed with software to allow for the organization and display of said digital medical data (i.e. single keystroke brings up display of current medical conditions, existing conditions, and known allergies)(page 13, lines 17-31).

As to claim 7, Yeager discloses the apparatus of claim 1 wherein the interface wand is capable of transmitting or receiving wireless digital information from the said bodily worn device using optical or other wireless- non contact means (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion)(page 5, lines 18-23)

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As to claim 8, Yeager discloses the apparatus of claim 1 wherein the base unit is capable of receiving said digital records in a wireless fashion (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion ... communication interface 156 can optionally communicate with a remote data terminal to provide access to database system 76 or to a local hospital or emergency medical center for data transmission for emergency room notification)(see Fig. 1, page 5, lines 18-23 and page 13, lines 5-14).

As to claim 9, Yeager discloses the apparatus of claim 1 wherein the base unit is capable of storing and organizing the medical records and critical information into prioritized pages for display and viewing (Fig. 7A and 7B).

As to claim 10, Yeager discloses the apparatus of claim 1 wherein the base unit contains software for the logic control of receiving said digital records, organizing said records in priority fashion and displaying said prioritized records on the display screen (i.e. allow the user to view the first of three medical screens, i.e., conditions, medications, allergies. The EXE button is pressed to view each screen)(Fig. 7A and 7B and page 13, lines 17-31).

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As to claim 11, Yeager discloses the apparatus of claim 1 wherein the base unit is capable of archiving and storing multiple digital patient records for retrieval and review (page 7, lines 20-27).

As to claim 12, Yeager discloses the apparatus of claim 1 wherein the patient module is capable of interfacing with an existing emergency room patient monitor and receiving said wireless transmission of said medical records for display on said existing patient monitor in an emergency situation (i.e. optionally transmit the pertinent medical data forward to the emergency room staff using facilities equivalent to those used to forward EKG data)(page 6, lines 19-27).

As to claim 13, Yeager does not explicitly disclose the apparatus of claim 1 wherein the patient module contains an interface Printed circuit board with electronic contact pads, or other suitable means, for transmitting power to the module board and for transmitting and receiving said digital patient medical records.

However, Sellers discloses wherein the patient module contains an interface Printed circuit board with electronic contact pads, or other suitable means, for transmitting power to the module board and for transmitting and receiving said digital patient medical records (i.e. electronics module includes printed circuit board ... processes signals from patient electrodes ...)(col. 4, lines 51-65, col. 5, lines 18-34 and col. 6, lines 3-10). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the patient module contains an interface Printed circuit board with electronic contact pads, or other suitable means, for

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transmitting power to the module board and for transmitting and receiving said digital patient medical records as disclosed by Sellers within the Yeager system for the motivation of recording and analyzing physiological data from a patient that is convenient to the patient without requiring specialized computers (col. 1, lines 49-57 and col. 2, lines 48-62).

As to claim 14, Yeager discloses the apparatus of claim 1 wherein the patient module contains an interface wand and electronic cable for capturing said digital records from said bodily worn device, using non-contact wireless means, and transmitting said records to the patient monitor for storage and display (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion ... probe I/O port 160 and data probe 32)(see Fig. 1 and Fig. 8, page 5, lines 18-23)

As to claim 15, Yeager discloses the apparatus of claim 1 wherein the system contains software and logic for the seamless storage, wireless transmission, receiving, prioritizing, creation of readable pages and displaying of said pages on a computer screen, patient monitor screen or other appropriate display device (Fig. 7A and 7B and page 5, lines 2-14).

As to claim 16, Yeager discloses a method for storing, retrieving or organizing medical records and other vital personal information from bodily worn storage devices (i.e. medical

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information storage system including a portable data storage device worn by a person)(see abstract, Fig. 1), comprising:

providing a bodily worn storage device capable of storing digital medical records and other vital personal health/emergency information (i.e. portable data storage device unit 22 includes datacell which contains medical information specific to person wearing device)(page 5, lines 5-15, line 28 - page 6, line 2 and Table 1) and a means of transmitting and receiving said digital medical records to and from the bodily worn device in a wireless fashion from a wireless receiving transmitting wand which would be either attached to a portable storage device or a patient monitoring device (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion)(page 5, lines 18-23) and be capable of displaying said medical data and records on a computer display screen for use in a medical emergency or other situation (i.e. handheld reader displays the medical data on the display screen including conditions, medications, allergies ... provides rapid access to critical patient medical data for paramedics, ER response teams and other medical personnel)(page 13, lines 17-30 and page 14, lines 1-6) and a means of transmitting said medical records from the portable field unit to a base unit for display and review by a medical professional (i.e. handheld reader displays the medical data on the display screen including conditions, medications, allergies ... communication interface 156 can optionally communicate with a remote data terminal to provide access to database system 76 or to a local

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hospital or emergency medical center for data transmission for emergency room notification)(page 13, lines 5-14 and 17-30)

Yeager does not explicitly disclose

transmitting said medical records to a base unit for storage and archival purposes

However, Sellers discloses transmitting said medical records to a base unit for storage and archival purposes (i.e. wireless data modem permits transmissions and reception of data through cellular telephone network ... communicates and transmits information with a remote computer system)(col. 7, lines 54-67 and col. 8, line 26 - col. 9, line 10). It would have been obvious to one of ordinary skill in the art at the time of the invention to include transmitting said medical records to a base unit for storage and archival purposes as disclosed by Sellers within the Yeager method for the motivation of providing subsequent diagnosis of a patient who is remotely located from a medical facility (col. 3, lines 37-55).

As to claim 17, Yeager discloses the method of claim 16 further including organizing the digital medical records stored in the bodily worn device into electronic pages which are in a medically significant prioritized manner with most critical information in a life threatening situation be accessible first and lesser medical information and personal information be accessible secondary (i.e. allow the user to view the first of three medical screens, i.e., conditions, medications, allergies. The EXE button is pressed to view each screen)(page 13, lines 17-31).

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As to claim 18, Yeager discloses the method of claim 16 further including transmitting said digital medical information from the bodily worn device to the portable field unit using optical or other wireless means via a wand or other suitable means (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion)(see Fig. 1, page 5, lines 18-23).

As to claim 19, Yeager discloses the method of claim 16 further including means of storing, organizing, prioritizing and displaying said digital medical records on the portable unit for emergency medical treatment (i.e. single keystroke brings up display of current medical conditions, existing conditions, and known allergies)(page 13, lines 17-31).

As to claim 20, Yeager discloses the method of claim 19 further including a means of transmitting the said medical records from the portable field unit via wireless or wired means to a base unit (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion)(see Fig. 1, page 5, lines 18-23).

As to claim 21, Yeager does not explicitly disclose the method of claim 16 further including a means of transmitting said digital medical records from the bodily worn device to a

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multi use patient monitor via wireless non contact means (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion)(see Fig. 1, page 5, lines 18-23).

As to claim 22, Yeager discloses the method of claim 21 further including a means of organizing , prioritizing and displaying said medical records on the patient monitoring screen for emergency medical or other medical usage (i.e. single keystroke brings up display of current medical conditions, existing conditions, and known allergies)(page 13, lines 17-31) .

As to claim 23, Yeager discloses the method of claim 20 further including a means of transmitting said digital medical records from the portable field unit to a base unit via wireless or wired means (i.e. medical information from datacell 24 can be accessed by handheld reading device 30 which includes datacell probe for electronically reading information from datacell 24 in wireless fashion ... communication interface 156 can optionally communicate with a remote data terminal to provide access to database system 76 or to a local hospital or emergency medical center for data transmission for emergency room notification)(page 5, lines 18-23 and page 13, lines 5-14.

As to claim 24, Yeager discloses the method of claim 23 further including a means of organizing, prioritizing and displaying said medical records within the base unit for emergency

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medical treatment (i.e. allow the user to view the first of three medical screens, i.e., conditions, medications, allergies)(page 13, lines 17-31).

As to claim 25, Yeager discloses the method of claim 24 further including a means of prioritizing medical records in a medically significant fashion so most critical life saving medical information, tailored to the individual wearing said bodily worn device, is displayed first in a medical emergency and . secondary medical information is displayed secondary on subsequent sequential pages (i.e. allow the user to view the first of three medical screens, i.e., conditions, medications, allergies. The EXE button is pressed to view each screen)(page 13, lines 17-31).

As to claim 26, Yeager discloses the method of claim 16 further comprising a means to allow for a common software language so that the digital information and medical records within the bodily worn device is compatible with the portable unit, the patient monitor and the base unit in a seamless and efficient manner (i.e. database management system hosted on a Windows based computing platform)(page 7, lines 20-27).

As to claim 27, Yeager discloses the method of claim 16 further comprising a means of updating an individuals digital medical records within the bodily worn device via transmission of updated data from the base unit or portable unit to the bodily worn device via wireless or wired means (see Fig. 1, units 26 and 28 and page 5, lines 14-18).

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As to claim 28, Yeager discloses the method of claim 16 further comprising a means of erasing data within a bodily worn device and re-writing new and/or updated digital medical records within the bodily worn device via wired or wireless transmission from the portable field unit or the base unit (see Fig. 1, units 26 and 28 and page 5, lines 14-18 and page 11, line 9 - page 12, line 11).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. Pat. No. 6,188,407 discloses a reconfigurable user interface for a modular patient monitor.

b. "Wearable computers" discloses the use of medical cards that store patient medical records.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander Kalinowski, whose telephone number is (703) 305-2398. The examiner can normally be reached on Monday to Thursday from 6:30 AM to 4:00 PM. In addition, the examiner can be reached on alternate Fridays.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached on (703) 305-9588. The fax telephone number for this group is (703) 305-7687 (for official communications including After Final communications labeled "Box AF").

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor, receptionist.



Alexander Kalinowski

Patent Examiner

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June 16, 2002